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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,067	08/16/2001	David B. Weiner	UPAP0025-100	4038
34136	7590	12/13/2007		
Pepper Hamilton LLP 400 Berwyn Park 899 Cassatt Road Berwyn, PA 19312-1183			EXAMINER KELLY, ROBERT M	
			ART UNIT	PAPER NUMBER
			1633	
			MAIL DATE	DELIVERY MODE
			12/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/719,067

Applicant(s)

WEINER ET AL.

Examiner

Robert M. Kelly

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 10, 14-16 and 40-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 10, 14-16, 40-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and response of 9/26/07 are entered.

Claim 10 is amended.

Claims 40-45 are newly presented.

Claims 9, 10, 14-16, 34 and 40-45 are presently pending and considered.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Applicant is advised that should 10 be found allowable, claims 41 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The claims comprise duplicate language and duplicate dependencies from the independent claims. Specifically, the independent claims differ in that Claim 9 is broader for encompassing any direct administration, while Claim 40 is limited to direct injection, which precludes topical administrations, lavage of surface tissues, etc. However, each of the dependent

Art Unit: 1633

claims encompass only the same options for administration, which can only be affected by direct injection into the tissues.

35 USC 112, first paragraph – Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

While the rejection of Claim 10 is withdrawn, Claims 9-10, 14-16, and 34 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for direct administration to the site proximal to the lymphnode, does not reasonably provide enablement for any method of delivery which transforms macrophage cells at the site, for reasons necessitated by the amendments. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is noted that the rejection is based on the newly proposed claim 40, and dependent claims, which demonstrates that Claim 9 and dependent claims are broader than direct injection.

Specifically, direct administration is noted to encompass such things as topical administration (SPECIFICATION, p. 11, paragraph 2).

However, such direct administration was known at the time of invention to be generally precluded due to the skin posing a barrier to such transfection (e.g., Zhang, et al. (1996) Biochemical and Biophysical Research Communications, 220: 633-636, ABSTRACT). It is noted that Zhang demonstrates the ability to specifically transform skin cells through electric

Art Unit: 1633

field application, however, Zhang does not demonstrate that macrophages are similarly transformed, and Applicant has no specific direction to transform the cells via electric field application.

Hence, the Artisan would have to experiment to determine those embodiments which can transform the macrophages sufficiently and drain to the lymph node target, which is undue as it amounts to inventing subject matter specifically encompassed for Applicant.

Hence, the claims are not enabled for those embodiments not directed to direct injection.

The following Art rejections are made in light of the recent decision by the Supreme Court of the United States: KSR v. Teleflex, 550 US --, 82 USPQ.2d 1385 (US 2007), which demonstrates the rigid application of the TSM test is incorrect, and no specific motivation is required, and hence, the present rejection is non-final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 10, 15-16, 34, and 40-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over US PAT APP NO 2004/0063652 to Jolly, Kataoka, et al. (1997) J. Biol. Chem., 272(29): 18209-15, US PAT NO 5,783,567 to Hedley, et al., Samlowski, et al. (1988) Regional Immunology, 1(1): 41-55, US PAT NO 5,763,416 to Bonadio, et al.

Art Unit: 1633

Jolly teaches the use of plasmids (e.g., paragraph 0037) to effect the transformation of macrophage cells, to effect killing (e.g., paragraphs 0067-71) and for general secretion of proteins that block pathogenic interactions local to the cell (paragraph 0155), which requires secretion signals.

Kataoka teaches the human CD156 gene, and its promoter sequence as specific for macrophage expression, as well as the structure of such promoters (p. 18215).

Hedley teaches the transformation of macrophages of the draining lymph nodes by subcutaneous injection (e.g., col. 8, paragraph 3), and Samlowski teaches that macrophages were known to drain to the lymph nodes local to the site of injection (e.g., ABSTRACT), hence, macrophages drain locally and not distantly.

Bonadio teaches that the SV40 polyA signal is a standard signal for termination of transcripts (e.g., EXAMPLE IX).

From the confluence of this, it is clear that Jolly teaches transfection of macrophages *in vivo* with plasmids, Hedley and Samlowski teaches that it transformation of the macrophages will lead to transfected cells in the draining lymph nodes, and Kataoka and Bonadio teach the required signals for expression of a gene in macrophages.

Therefore, at the time of invention, the method would have been obvious. The Artisan would choose a site local to the lymph node target because the macrophages were known to drain to local lymph nodes. Still further, the Artisan would inject the plasmid by IM injection in order to deliver it to a lymph node local to the muscle injection site. Moreover, the Artisan would have expected success, as the transformation of macrophages was already well known and the

Art Unit: 1633

draining of such macrophages to lymph nodes was well known in the Art. In addition, the obtained result would necessarily be obtained as the macrophage is secreting the protein.

Arguments of specific motivation are now precluded by KSR v. Teleflex. In essence, Applicant's claims reflect what is already known in the Art to occur and is simply another method that the Artisan would be capable of performing prior to the invention in order to get proteins into the lymph nodes. In addition, without a requirement of the amounts of protein or some other limitation such that the Artisan would not expect it to work, there is a reasonable expectation of success.

CONCLUSION

No Claim is allowed.

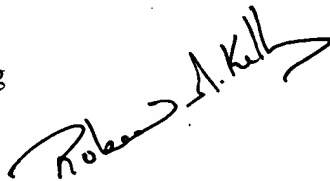
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1633

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Kelly, Ph.D.
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A handwritten signature in black ink, appearing to read "Robert M. Kelly", is written diagonally across the page.